THE HISTORY OF INFORMED CONSENT

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Informed consent for surgical procedures is a relatively new trend in the practice of surgery. For thousands of years physicians felt that deception was an integral part of the practice of medicine. Over the last 150 years, the concept of physicians establishing a "standard of care" has gradually been replaced by the idea that the well-informed patient can be the master of his/her own body. Thus, the practice of informed consent has emerged as surgery has become more patient-oriented.

EARLY HISTORY

In ancient Greece patient participation in decision making for medical treatment was considered undesirable. It was generally accepted that the physician's primary task was to inspire the confidence of the patient in the treatment. Any disclosure of possible difficulties might erode patient trust. Later, during medieval times, medical writing encouraged doctors to use their conversations with patients as an opportunity to offer comfort and hope while emphasizing the need for the doctor to be manipulative and deceitful. To effect a treatment cure, it was widely felt that authority must be coupled with obedience.[9]

During the Era of Enlightenment, new views emerged stating that patients had the capacity to listen to the doctor, but it was still felt that deception was necessary to facilitate patient care. During the 1800's the medical profession was split over whether to disclose a dire prognosis to a patient. However, most physicians of the time argued against informing patients of their condition.[9]

The doctrine of assault and battery has its roots in early English Common Law. This Doctrine forms the basis for the possible "injury" or "liability" incurred from surgery without proper consent.[3] Common Law is the combination of customs, traditions, and case law; it is distinct from legislative law which is law enacted by a governing body.[7] Many of these English Common Law doctrines have influenced our tort system of justice. Assault is a threat by one person to do bodily harm to another while battery is the actual touching of a person by another. Therefore, the theory of tort battery became the unauthorized touching of a person by another.[3]

As the concept of informed consent gained popularity during the twentieth century, the courts extended the English Common Law Tort doctrine of negligence to the field of surgery by equating negligence with breach of duty and breach of duty with an incomplete patient consent. Currently, the failure of a physician to provide adequate information to the patient about his/her own treatment is interpreted by the courts as a breach of duty by the physician.[3,9]

With this early background, let us turn in chronological order to some of the more significant legal cases of the twentieth century and then examine how these cases have shaped the current doctrine of informed consent.

Luka v. Lowrie, 136 N.W. 1106, Michigan 1912

In this case, a surgeon believed that an emergency amputation was necessary to save a child who had sustained a crush injury to his foot. Before proceeding with procedure the surgeon consulted four other physicians, all of whom agreed that an emergency amputation of the child's foot was necessary. The child's parents were unavailable to discuss the matter. Subsequently, the court ruled that if they had been available, the parents would have agreed with the need for an emergency amputation when informed that multiple physicians had been consulted, all of whom agreed with the need of an emergency procedure.

Schoendorff v. Society of New York Hospital, 211 N.Y. 215,105 N.E. 92,1914

This case has had probably the most impact on the doctrine of informed consent, and first established that the patient was an active participant in the treatment decision process. In this case, Justice Benjamin Cardozo summarized

> "every human being of adult years in sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patients consent commits a battery for which he is liable in damages".

Dicenzo v. Berg, 16 A2d 15, Pennsylvania, 1940

In this case, the court supported the defendant's (the physician) attempt to supply the patient with a description of the procedure to be performed even though the plaintiff (the patient) was not pleased with the outcome. The

patient had originally consented to a surgical procedure on his neck but was quite concerned about scarring the exposed portion of his neck. After the surgery, the patient felt that the surgeon's incision and subsequent scar were inappropriate, and subsequently brought suit. The court eventually ruled that the surgeon must be given sufficient latitude within the boundaries of the patient's consent to operate. The court determined that the surgeon had obtained adequate consent from the patient and had placed the incision appropriately and therefore should not be liable.

Prince v. Massachusetts, 321 US 158, 1944

Early in this century, the courts established a concept that has remained: parents cannot refuse treatment to their children on the basis of religious beliefs. In this case the Supreme Court stated "Parents may be free to become martyrs themselves, but it does not follow that they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves." Two examples are members of the Jehovah's Witness Church denying medically-necessary blood transfusions to their children and Fundamentalist Christians in southern West Virginia requiring children to handle snakes during worship services and refusing them medical attention once bitten. In both of these situations the parents would be subject to child neglect laws.

Bang v. Charles T. Miller Hospital, 251 Minn, 427.88 N.W. 2d 186, Minnesota, 1955

This case established that the patient was entitled to know inevitable risks or results of surgery. In this case an elderly male patient consented to a transurethral prostatectomy. He was not specifically informed prior to the procedure that the accepted surgical technique would in all likelihood leave him sterile post-operatively. The surgeons in this case were found liable.

Corn v. French, 71 Nev. 280,289 P. 2d 173, Nevada, 1955

Corn v. French established that the surgeon must not misrepresent the surgery to be performed. In this case, after examining the patient, the physician advised that she undergo a test for a possible malignancy of the breast. The patient subsequently asked the doctor if he intended to remove her breast, to which the physician replied "no". The patient then signed a written form consenting to a "mastectomy" even though she received no explanation of the procedure. Inevitably, the physician was found liable for an unauthorized procedure.

Natanson v. Kline, 350 P2d 1093, Kansas, 1960

In this case the court found that the patient, not the surgeon, must be the final decision maker. The final summary read: "A man is the master of his own body and he may expressively prohibit the performance of life-saving surgery or other treatment." A doctor may believe that an operation or other form of treatment is desirable or necessary, but the law does not permit him to substitute his own judgement for that of the patient by any form of misrepresentation or deception.

Darrah v. Kite, 32 A2d 108, New York, 1969

The verdict in this case established that each invasive diagnostic test requires a separate consent. This lawsuit resulted when the parents consented to having their child admitted to the hospital for "routine" brain tests in order rule out a developmental disorder. The physician then proceeded with a complete workup including invasive tests. Ultimately, the court ruled against the physician finding that "routine" brain tests did not include significant invasive studies and established that patients should not be admitted to a hospital under a general consent of admission and then receive a wide variety of invasive diagnostic tests without separate specific consents.

Green Case, 296 A.2d 681, Pennsylvania, 1971

In this case the court authorized blood transfusions for a Jehovah's Witness child with paralytic scoliosis. This patient had a 94° curve with pulmonary and cardiac impairment. The mother consented to a spinal fusion, but refused to consent to any blood transfusions. The court ruled that without the scoliosis surgery (and the incumbent blood transfusions) the patient would be considered under state law a neglected child because he did not receive the surgery required for his well-being. Subsequently, a court- appointed guardian authorized the scoliosis surgery and subsequent blood transfusions.

In re Osborne, 294 A2d 372, Washington, D.C., 1972

The courts have traditionally held that if a patient with dependents refuses a blood transfusion necessary to save his or her own life, the transfusion can be given. In this situation an individual's religious freedom can be superseded by the right of society to reduce the number of people on welfare and attempt to preserve the family unit. Over time, however, the courts have developed limitations to these restrictions based mainly on the doctrine of informed consent. An example of this is the Osborne case where a thirty-four-year-old married man with two children was severely injured when struck by a tree. The patient refused to accept blood transfusions on the basis

of religious beliefs. The patient was deemed fully competent and expressed the desire to obtain "everlasting life" rather than receive a blood transfusion. Subsequently the courts found that his wife was competent to run the family business and provide for the children. Additionally, if the wife was unsuccessful in managing the family business, then the wife's parents and brother affirmed that they would care for the children if necessary. The court then could find no obvious interest to society in restricting this patient's religious freedom, and so a blood transfusion was not ordered.

Cobbs v. Grant, 502 P2d 1 California, 1972

Prior to this ruling, courts in most states had upheld the prevailing "standard of practice" rule with respect to risk disclosure. The decision in this case posed the more liberal patient-oriented concept of the disclosure of risks:

> "Had the patient, judged as a reasonable and prudent person, been provided adequate information about the procedure and its risks prior to consenting to the procedure, or if some material risk had been presented, would the patient have refused to proceed with surgery?"

In this case the plaintiff (patient) underwent surgery for a duodenal ulcer and an artery at the base of the spleen was lacerated resulting in splenectomy. The patient had not been informed that injuries to the spleen occur in approximately 5% of duodenal ulcer repairs. Subsequently the patient sued for malpractice at time of surgery and for negligence on the part of the physician for failure to obtain a complete informed consent. The jury returned a verdict in favor of the plaintiff and assessed damages against the hospital and the surgeon.

Canterbury v. Spence, 464 F2d 772, Washington, D.C., 1972

The courts have generally affirmed that rare risks of surgery do not need to be specifically discussed as part of the consent unless these rare risks pose critical consequences. In this case Mr. Canterbury sought medical treatment for back pain from an neurosurgeon, Dr. Spence. Dr. Spence performed a myelogram which demonstrated a filling defect at the T4 level consistent with a herniated thoracic disc. Dr. Spence then proceeded to recommend the laminectomy which was performed. Preoperatively Dr. Spence did not provide a thorough description of the procedure and did not indicate that paralysis was a known complication to the procedure. Additionally, he did not indicate any alternative methods of treatment to Mr. Canterbury. Mr. Canterbury underwent an uneventful laminectomy and did well post-operatively until he fell from bed incurring a T4 complete paraplegia. In the lawsuit that followed the court held that Dr. Spence had been negligent in obtaining a complete consent. The court also stated that in consenting a patient the following must be included in order to assure that the patient has adequate knowledge of the procedure, the diagnosis and differential diagnosis, required diagnostic procedures, detailed description of the surgical procedure with any postoperative treatment necessary, the risks of the surgical procedure, any alternative methods of treatment, and expected results.

Richardson, 284 So.2d 195 Louisiana, 1973

The courts had established that when parents grant consent for children the procedure to be performed must have some specific benefit for the patient. In the Richardson case a child developed renal failure requiring renal transplantation. A second child in the Richardson family who was mentally retarded was deemed a renal transplantation candidate to the first child. The court later ruled that the parents could not authorize the mentally retarded child to become a renal transplantation donor because there was no specific derived benefit to the mentally retarded child.

Reif v. Weinberger, 372 F.Supp. 1196, District Court Washington, D.C., 1974

This case established that any consent given under physical or mental duress is invalid. In this case tubal ligation was recommended to a patient on welfare. The patient was also advised that if she did not have the tubal ligation, her welfare benefits would be significantly reduced. The District Court of Washington, D.C. determined that this was consent given under duress and not a voluntary consent. The consent was therefore deemed invalid and the surgeon was found liable for assault and battery.

In re Melideo, 390 N.Y.S. 2d 523, New York, 1976

In the Melideo case, Mrs. Melideo received a dilatation and curettage of the uterus for diagnostic purposes. After surgery, she developed significant bleeding. Mrs. Melideo refused blood transfusions on the basis of her religious belief against blood transfusions. Subsequently a court order was sought by the hospital in an attempt to authorize a transfusion against the expressed desires of the patient. The court determined that a patient may decline treatment and that to order such a treatment that is expressively refused by the patient on religious grounds would be a violation of that patients constitutional protection of religious freedom. Subsequently, the transfusion was not ordered.

Robert Quachenbush, 383 A2d 785, New Jersey, 1978

This case illustrates that medically necessary treatment other than blood transfusions can be refused for reasons other than religious reasons. Additionally, this case

points out that a patient's refusal of medically necessary treatment does not determine competence in treatment decisions.

Robert Quachenbush was an elderly male with a long history of peripheral vascular disease admitted to a hospital for treatment of bilateral lower leg gangrene. His temperature was elevated and cultures were positive for clostridium. The patient's lower extremities were black and drained purulent fluid; however, the use of IV antibiotics produced a temperature defervescence. The patient's physician recommended bilateral above the knee amputations on an emergent basis. Mr. Quachenbush, however, stated that he had objected to most medical care for over forty years and subsequently refused the recommended surgical debridements and amputations. The surgeon believed that Mr. Quachenbush was suffering from organic brain syndrome and presented the situation to hospital administrators. The hospital in turn petitioned the court to have a guardian appointed to make medical decisions for Mr. Quachenbush, who was felt to be incompetent to make treatment decisions because of his organic brain syndrome.

The court, however, found that refusal for above the knee amputations interfered with the accepted medical treatment for his condition. Mr. Quachenbush did have an understanding of the proposed procedure with his risk in expectations. The court felt that Mr. Quachenbush had a valid concern about the risks and subsequent rehabilitation after bilateral above the knee amputations. Therefore, the court found the patient to be competent to decide on surgical alternatives and ruled that the amputations could not be required based on the right to privacy under Federal Constitutional Law.

Bech v. Lovell, 362 So.2d 802 Louisiana, 1978

The State Court ruled that a spouse or family member cannot consent for surgery in place of the competent patient. The only exception to this situation would be the added presence of a medical emergency where the otherwise competent patient might be unable to participate in the consenting process. A family member's consent for an otherwise competent patient who had been sedated would therefore be inadequate. A second situation that could arise is the physician obtaining consent from a family member because the unavailability of the patient; such a consent would be considered inadequate based on this ruling.

Truman v. Thomas, 27 Cal.3d 285, California, 1980

Although the patient has a right to refuse tests or treatment, the courts have established that the physician has a duty to inform patients of the risks of refusal. In Truman v. Thomas, the patient rejected a family doctor's advice to have a pap smear. Subsequently, on repeated occasions the family doctor recommend a complete physical examination including a pap smear. The patient refused each of these pap smears and the physician assumed that the patient knew the purpose of the test and did not specially discuss with her the risks of failing to have the pap smear. Eventually, the patient developed advanced cervical cancer. In the lawsuit that followed, the California Supreme Court overturned a lower court ruling and stated that the physician had the duty to disclose all information to patients, including the possible outcome of refusing recommended screening tests for cancer.

Perna v Pirozz, 92 N.J. 446,457 A.2d 431, New Jersey, 1983

Surgery performed by a person other than the surgeon named by the patient at the time of consent constitutes battery. Additionally, the originally authorized surgeon who obtained the consent but failed to perform the surgical procedure is therefore liable for malpractice on the basis of breech of duty.

Precourt v. Frederich, 395 689,481 N.E.2d 1144 Massachusetts, 1985

The decision handed down in this case set limitations upon a physician's duty of risk of disclosure at the time of consent and could be interpreted as a "Tort Reform" case. In this case a patient underwent a surgical procedure on the eye for which prednisone was given postoperatively to control inflammation. Subsequently, the patient developed aseptic necrosis of both hips and a lawsuit resulted. Even though the Physician Desk Reference (PDR) lists aseptic necrosis of the hips as a complication from prednisone therapy, a witness for the defense testified that a library search of articles on the subject showed no reports of aseptic necrosis of the hips developing secondary to the postoperative use of prednisone after eye surgery. Therefore, a higher court overturned a lower court's jury verdict in favor of the plaintiff stating "in this case there was no evidence of the likelihood that a person would develop aseptic necrosis after taking prednisone or that Dr. Frederich knew or should of known that the likelihood was other than negligible.

Large v. Superior Court of Arizona, 714 P.2d 399, 1986

This case demonstrates that competence for consenting to surgical procedures may differ significantly from the competence necessary to execute other activities. In Large v. Superior Court of Arizona a women with organic brain syndrome and poor cognitive function was admitted to the hospital with a hip fracture subsequent to a fall. The risks and expected outcome of surgical repair for hip fracture was discussed with the patient by the operating

surgeon. At that time the patient was felt to understand the material presented and subsequently consented to the procedure. At the same time she executed a will in the presence of a lawyer. Postoperatively, the patient died and both the consent to surgery and her stated will were reviewed by the court. The court found that the will was invalid due to her lack of testamentary competence (the patient did not know the extent of her property or her family members). However, the surgical consent was considered valid by the court because the patient was able to understand the procedure, its risks, and potential benefits.

Younts v. St. Francis Hospital, 469 P2d 338 (1986)

In many states adolescents over fourteen years of age are considered adults with the right of privacy, confidentiality and competency to consent to surgical procedures. In Younts v. St. Francis Hospital a seventeen year old girl presented with a distal phalanx tuft fracture and skin avulsion after trapping the finger in a car door. The girl's mother was under general anesthesia at the time of her injury and her father (divorced from the mother) could not be located. After several attempts to locate the father the procedure to be performed was explained to the patient along with its risks, benefits, and alternatives. She subsequently consented to the procedure but a lawsuit followed. Ultimately, the court held that the patient, even though she was a minor, understood the nature of the surgery, possible risks, and potential benefits. Therefore, the consent was found to be valid.

With the above case decisions in mind, some conclusions about the doctrine of informed consent can be drawn. Whenever a physician obtains a consent from a patient, that physician should be mindful of the conditions necessary for informed consent, the information requirements necessary for an informed consent, patient competence in delivering his/her own consent and how consents in an emergency situations may be obtained.

CONSIDERATIONS FOR VALID CONSENT

As viewed by the courts, a consent is the authorization by a patient to have a certain medical treatment or surgery performed on that person. A consent may be expressed or implied. An expressed consent is one that is either written or spoken by the patient. An implied consent is one demonstrated by the acts of a patient. An example of an implied consent might be the presence of a patient in an examining room of a doctor's office. Although this patient has not formally said or written that he or she consents to a physical examination by a physician, he or she is present on his or her own free will and offers no resistance to examination. Therefore, a complete consent form is not a legal paper but merely a documentation of the patient's expressed desires for medical or surgical treatment.

For a consent to be valid it must be obtained from a knowledgeable patient who understands the procedure to be performed, as well as that procedures risks, complications, and possible alternatives. Additionally, the consent must be voluntarily given and not received under duress or threat. Most importantly, the consent must be given by a patient who is deemed competent to offer a medical consent.[3]

INFORMATION NECESSARY FOR A CONSENT

In Canterbury v. Spence 464 F2d 772 Washington, D.C. 1972, the court held that the consent must address six different information requirements for the patient to be truly informed. 1) The patient must be aware of the diagnosis. 2) The patient must be aware of any diagnostic procedures necessary to ascertain the diagnosis. 3) The surgical procedure must be described in a way that the patient understands. 4) The patient must be informed of any inevitable risks from surgery (frequent outcomes of surgery) and any collateral risks (any complication arising indirectly as a result of surgery). 5) The patient must be informed all alternative methods of treatment both surgical and conservative, and 6) the expected results and their probability should be discussed in sufficient detail with the patient prior to surgery.

CONSENTING COMPETENCE

For a patient to consent to a surgical procedure or a medical treatment he or she must be deemed competent from a medical point of view which, as pointed out earlier, may differ significantly from a legal point of view (Large v. Superior Court of Arizona, 714 P2d 399, 1986). The patient is considered medically competent and able to give consent when that person understands the procedure to be performed, appreciates the reason for the proposed procedure, and is aware of the risks of the procedure and the expected outcome. If the patient is considered incompetent to give a consent, the consent may be obtained from the next of kin (mother, father, wife, sibling, or child) or the statute of *parens patriae* may be evoked by the courts. A statute of *parens patriae* allows the court to appoint a guardian for a patient for the purposes of medical decision making.

Historically, children have not been considered incompetent to make medical decisions; however, in some states adolescents fourteen years or older are considered adults for medical consent purposes. Exceptions to the historical trend, however, include: 1) children or adolescents who are pregnant, 2) children or adolescents who are parents, 3) children or adolescents deemed self-reliant in that they

are living away from home and are independent, 4) children or adolescents who are members of the Armed Forces, and 5) adolescents who are considered mature minors being financially independent and self-reliant despite living at home with parents.[1]

EMERGENCY CONSENT

There are certain exceptions to the previously mentioned criteria for a valid informed consent. Such exceptions exist for emergency consenting. In this situation the physician may proceed with treatment without formal consent from the patient. This exception to the formal consent process was created based on the understanding that the patient, if able, would consent for the proposed procedure. However, frequently certain situations arise where severely injured patients cannot give consent and family members are unavailable. In these situations, treatment frequently cannot be delayed and it must be assumed by the physician that the patient or the family would provide authorization for the proposed treatment given the urgency of the situation. It is generally felt that for the physician to proceed in an emergency situation without consent the following must exist: 1) a true medical emergency, 2) the physician is truly unable to obtain consent from the patient or next of kin, 3) the proposed treatment is for the ultimate benefit of the patient.[2]

CONCLUSION

The doctrine of informed consent is a relatively new idea in the history of medical practice. The ancient practitioners of medicine adopted a paternalistic attitude towards patient care, and seldom involved the patient in the decision-making process. In the 18th and 19th centuries, the concept of assault and battery arose from English Common Law and established the idea that the surgeon must receive authorization from a patient before performing surgery or otherwise be liable for breach of duty. During the 20th century, various legal decisions have gradually swung the pendulum from a paternalistic, "standard of care" decision making approach to a more patient-centered concept:

"a man is the master of his own body...", (Natanson v. Kline, 350 P2d 1093, Kansas, 1960).

A valid consent, then, represents the evolutionary process from paternalistic medicine to patient-centered medicine. The consent must be given voluntarily by a competent, knowledgeable patient who understands the proposed treatments with their incumbent risks and alternatives.

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